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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,874	12/20/2001	Chika Nakanishi	217408US0CONT	4217

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EXAMINER	
MORRIS, PATRICIA L	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,874	NAKANISHI ET AL.	
	Examiner	Art Unit	
	Patricia L. Morris	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,20-25 and 27-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8,10,12,14,15,21-23,28-30,33 and 34* is/are rejected.

7)☒ Claim(s) *2-4,9,11,20,24,25,27,31 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15, 20-25 and 27-34 are under consideration in this application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 17, 2005 has been entered.

Election/Restrictions

Applicants allege that the examiner failed to examine the elected compound. This is a false allegation because the examiner did search the elected invention. Applicants are essentially claiming trillions of compounds and a laundry of uses that they expect the examiner to search all the inventions.

It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

Claim Rejections - 35 USC ∋ 103

The rejection under 35 USC 103 is hereby withdrawn in view of applicants' arguments in the instant response.

Claim Rejections - 35 USC ∋ 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Again, there is no enablement is shown for the treatment of any of the claimed diseases. The *in vitro* tests are insufficient to show the treatment of any and all unknown cerebrovascular disorders and neurodegenerative diseases, withdrawal symptoms after addiction to drug, AIDS, Parkinson's disease etc. There are no working examples anywhere in the specification.

Applicants merely supply some references drawn to unrelated compounds that have said uses. Applicants have failed to supply any **objective evidence** showing that the **claimed**

compounds actually treat any of the diseases. Applicants have essentially described a genus of trillions of compounds, mentioned a test, and told the public to figure our which ones (if any) will have the desired use. This is not the level of where "specific benefits exists in currently available form" Brenner v. Manson, 383 USPQ 519. The great majority of these have no treatments at all, and of those that do, none or virtually none been treated with such compounds as are disclosed here.

As pointed out by the court, in In re Surrey, 370 F.2d 349, 151 USPQ 724, 729 (CCPA 1966).

> "Manifestly, a disclosure which does not adequately establish compounds as useful for an asserted purpose does not adequately describe "how to use" those compounds either."

Again, the disclosure provides no indication of whether the compounds treat any disease of any claimed disease. Contra to applicants' arguments in the instant response, the silent as whether to any of the compounds treat any disease. Applicants now argue that US 6,350,762 discloses that the compounds have all the allege utilities when in the same response applicants argue that the prior art compounds are not the same as the instant compounds nor even suggest the instant compounds. Applicants cannot have it both ways.

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e., what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

The instant claimed invention is highly unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. In the instant case, the claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic and preventive effects of any and all diseases including all unknown diseases whether or not the disease is effected by antagonizing an N-type calcium channel would make a difference.

It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer's disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memtine, which blocks excess amounts of glutamate treats late stage Alzheimer's disease.

(URL:http://www.cnn.com/2003/Health/conditions/09/24/alzheimers.drug.ap/index.html)

Contra to applicants' arguments in the instant response, the guidance present in the specification is that of the compounds that are tested that some work, some don't work and some work to a weak extent. Note table 9 of the specification. The claims are drawn to the treatment of any and all diseases with the billions of compounds claimed in claim 1. Applicants even claim any and all unknown heterocyclic compounds.

The quantity of experimentation needed is undue. One skilled in the art would need to determine what disease out of all known diseases would be benefited by inhibiting a calcium

channel and then would further need to which of the claimed compounds would provide treatment of a disease.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment of any disease. As a result necessitating one of ordinary skill to perform an exhaustive search for which diseases can be treated by which compound of claim 1 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Thus, applicant= situation is much like that of In re Kirk, 153 USPQ 48: AWhat the applicants are really saying to those skilled in the art is take these compounds experiment, and find out what use they have≅. Undue experimentation would be required.

In view of the extreme difficulties that have been are still being encountered in the treatment of AIDs, AIDS related dementia, Alzheimer's disease, Parkinson's disease, etc., such utililites are unbelievable on their face, and therefore, they must be supported by sufficient evidence demonstrating such utilities. When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, In re Ferens, 163 USPQ 609.

In cases directed to chemical compounds, which are being used for their physiological/biological activity, the scope of the claims must have a reasonable correlation to

the scope of enablement provided by the specification. See In re Surrey, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group and In re Wiggins, 179 USPQ 421.

Claims 1, 5, 6, 10, 12, 14 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expressions a" lower alkyl group... hetero atom in the ring", "R^6 and R^7 may together form a ring....may have a subsituent" and "substituted" are employed with considerable abandon throughout claims 1, 5, 6, 10, 12, 14 and 26 with no indication given as to what the rings and substituents really are. One, one reading the indication of heterocyclic ring applied by applicants in R^6 and R^7, has no idea what size ring is being claimed, or where the hetero atoms are in this unknown ring or what the substituents may be. Moreover, the term substituted is employed in claims 1,5, 6, 10, 12, 14 and 26 with no indication of the variables The term contains is open-ended. What are the substituents on the pyridine and furyl rings?

One cannot tell from a simple reading of the claim what is being claimed. Also, one must figure which compound treats which disease. One must first conceive of the hetero ring. Further, applicants are claiming that the instant compounds can treat a staggering list of any and all diseases. Then one must, by preparing the compound himself, determine if the hetereo ring or substituents works or not. Where is the specific claiming and distinctly pointing out? How can applicants regard as their invention inexact concepts? The breadth of which they could not have possibly checked out with representative exemplification. The terms are not finite.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. Not a resin of general property ranges, but a pure compound. That compound used for any purpose is taken from the public in a 20-year monopoly to applicants. Then, the public is entitled to know what compound they cannot use. Yet, the claim is not specific to that compound. The public cannot tell what they may not use. How is a claim of the instant breadth defensible in an infringement action?

As applied to pure compounds, In re Cavallito and Gray, 134 USPQ 370, and In re Sus and Schaefer, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

The written description is considered inadequate here in the specification. Conception of the intended rings and substituents should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,8. 14, 15, 28-30, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 fails to clearly what is intended by applicants. There is no antecedent basis for the staggering list of additional heterocycles recited in claims 8, 14, 15, 28, 29, 30, 33 and 34. Now Claim 1 fails to claim the **elected piperidines.**

Allowable Subject Matter

Claims 2-4, 7, 9, 11, 20, 24, 25, 27, 31 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1, 5, 6, 8, 10, 12, 14, 15, 21-23, 28-30, 33 and 34 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
August 2, 2005